UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Jihan Darwish,	)	**CASE NO. 1:20 CV 1606**
	)	
Plaintiff,	)	**JUDGE PATRICIA A. GAUGHAN**
	)	
Vs.	)	
	)	
Ethicon, Inc., et al.,	)	
	)	**Memorandum of Opinion and Order**
Defendants.	)	

INTRODUCTION

This matter is before the Court upon defendants Ethicon, Inc. and Johnson & Johnson's Motion to Dismiss (Doc. 12). This is a products liability action involving a pelvic mesh product. For the reasons that follow, this motion is GRANTED in part and DENIED in part. Specifically, Count Three of the Complaint is dismissed and Counts One, Two, Four, and Five of the Complaint will proceed.

FACTS

Plaintiff, Jihan Darwish, filed this action against defendants Ethicon, Inc., Gynecare Worldwide, and Johnson & Johnson in this Court on the basis of diversity of citizenship. The

Complaint asserts state law claims for negligence and products liability in connection with injuries plaintiff sustained from the implantation of a pelvic mesh product.

For purposes of ruling on the pending motion, the facts asserted in the Complaint are presumed to be true.

On September 26, 2011, plaintiff had a Gynecare TVT Abbrevo Mesh product, Model No. TVTOML ("the product") surgically implanted to treat her stress urinary incontinence. Following the implantation of the product, plaintiff developed physical pain, permanent injury, and physical deformity. She lost income, as well as "impaired physical relations with her husband." On April 20, 2018, plaintiff had the product removed due to the pain and complications she had developed.

Defendants manufactured, designed, marketed, labeled, packaged, and sold the product. Defendants marketed the product through television, print, and internet advertising, as well as through sales representatives. The product was marketed as a safe medical device for the treatment of stress urinary incontinence.

In October 2008 and July 2011, the Food and Drug Administration issued "warnings regarding the complications and risks associated with" pelvic mesh products, such as the product. The product contains a monofilament polypropylene mesh. Despite claims that polypropylene mesh is inert, scientific evidence shows that this material "is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair [it] promote[s] a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with" with the product.

The product is also "unreasonably susceptible to degradation and fragmentation inside

the body; shrinkage or contraction inside the body; intense foreign body reaction; chronic inflammatory response; chronic wound healing; chronic infections in and around the mesh fibers; [and] nerve entrapment in the collagen scar formation." Defendants omitted and downplayed these risks and marketed the product as a safe medical device. While defendants made some of the problems associated with the product known to physicians, the "magnitude and frequency of these problems were not disclosed and were hidden from physicians."

Contrary to the representations defendants made to the medical community and patients, the product has a high rate of failure, injury, and complications, and requires "frequent and often debilitating re-operations," such as the one plaintiff underwent. There are "available feasible alternatives that do not involve the same risks."

The Complaint contains five claims for relief. Count One is a common law claim for negligence. Counts Two, Three, Four, and Five are claims for statutory products liability under the Ohio Products Liability Act ("OPLA"). These claims are asserted against all defendants.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "defendants") move to dismiss the Complaint. Plaintiff opposes the motion in its entirety.

STANDARD OF REVIEW

When considering a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the allegations of the complaint must be taken as true and construed liberally in favor of the plaintiff. *Lawrence v. Chancery Court of Tenn.*, 188 F.3d 687, 691 (6th Cir. 1999). However, the complaint must set forth "more than the bare assertion of legal conclusions." *Allard v. Weitzman* (*In Re DeLorean Motor Co.*), 991 F.2d 1236, 1240 (6th Cir. 1993). Legal conclusions and unwarranted factual inferences are not accepted as true, nor are mere

conclusions afforded liberal Rule 12(b)(6) review. *Fingers v. Jackson-Madison County General Hospital District*, 101 F.3d 702 (6th Cir. Nov. 21, 1996), *unpublished*. Dismissal is proper if the complaint lacks an allegation regarding a required element necessary to obtain relief. *Craighead v. E.F. Hutton & Co.*, 899 F.2d 485, 489-490 (6th Cir. 1990).

In addition, a claimant must provide "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 569 (2007). A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1955 (2009). Nor does a complaint suffice if it tenders "naked assertion[s]" devoid of "further factual enhancement." *Id.*

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it stops short of the line between possibility and plausibility of 'entitlement to relief.'

Id. at 1949 (citations and quotations omitted). *See also Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603 (6th Cir.2009).

ANALYSIS

I. Negligence (Count One)

Count One is a common-law claim for negligence.[1] Defendants argue that this claim should be dismissed on the basis that the OPLA abrogates common-law negligence claims for

[1] The parties do not dispute that, because the injury occurred in Ohio, Ohio law applies.

product liability.[2] According to plaintiff, because this claim is seeking economic damages it is not fully abrogated by the OPLA.

The OPLA abrogates "all common law product liability claims or causes of action." O.R.C. § 2307.71(B). However, this abrogation only extends to those claims that, "as pled, actually meets the statutory definition of a product liability claim." *Volovetz v. Tremco Barrier Sols., Inc.*, 74 N.E.3d 743, 753 (Ohio Ct. App. 10 Dist. 2016). The OPLA defines a product liability claim as one that:

> seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
>
> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
>
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
>
> (c) Any failure of that product to conform to any relevant representation or warranty.

O.R.C. § 2307.71(A)(13)(a)-(c). Accordingly, common law claims that do not meet this definition remain viable.

Relevant to here, if a plaintiff brings a common law product liability claim seeking only economic loss damages, the claim is generally not within the purview of the OPLA. *Simpson v.*

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[2] In their reply brief, defendants argue for the first time that the negligence claim must be dismissed for the additional reason that the Complaint does not provide any specific factual allegations explaining how defendants were negligent in the design and manufacture of the product. This argument is improperly raised in a reply brief and the Court declines to consider it. *See Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 553 (6th Cir. 2008) (issues raised for first time in reply brief are deemed waived).

Johnson & Johnson, 2020 WL 5629092, *3 (N.D. Ohio 2020); *Dates v. Ethicon, Inc.*, 2020 WL 3265537, *2 (S.D. Ohio 2020) (*citing LaPuma v. Collinwood Concrete*, 661 N.E.2d 714, 716 (Ohio 1996)). Indeed, "Ohio law permits ordinary consumers who are not in privity of contract with product manufacturers to bring claims such as negligent design and negligent failure-to-warn in order to recover damages for economic injury only." *In re Whirlpool Corp. Front-Loading Washer Products Liability Litigation*, 722 F.3d 838, 856 (6th Cir. 2013). *See also* O.R.C. § 2307.72(C) ("Any recovery of compensatory damages for economic loss based on a claim that is asserted in a civil action, other than a product liability claim, is not subject to [the OPLA], but may occur under the common law of this state or other applicable sections of the Revised Code.") These economic loss damages typically "encompass the change in value of a defective product or the indirect losses sustained as a result of a defective product such as the value of production time lost and resulting lost profits." *Dates*, 2020 WL 3265537 at *2 *(citing Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co.*, 537 N.E.2d 624, 629 (Ohio 1989)).

Here, the Complaint alleges that defendants were negligent in "failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Gynecare TVT Abbrevo Mesh." The Complaint seeks both economic and compensatory damages in connection with this claim.

Upon review, the Court finds that to the extent that plaintiff's negligence claim seeks compensatory damages for physical injury and emotional distress, this claim is abrogated by the OPLA. The Complaint alleges defendants were negligent in the design, manufacture, marketing, and selling of the product. The Complaint also seeks compensatory damages for plaintiff's personal injuries, pain, disability, suffering, and emotional distress. This claim clearly falls

within the OPLA's definition of a product liability claim. *See Huffman v. Electrolux North America, Inc.*, 961 F.Supp.2d 875, 880 (N.D. Ohio 2013) ("[I]t is now settled that the scope of a 'products liability claim,' as defined by OPLA, includes common-law negligence claims seeking compensatory damages."); *Simpson v. Johnson & Johnson*, 2020 WL 5629092, *4 (N.D. Ohio 2020) ("Courts have consistently held that a common law claim for negligent design, manufacture, inspection and failure to warn are abrogated.")

However, to the extent that the negligence claim seeks economic loss damages, it is not abrogated by the OPLA. While it is unclear to the Court what economic loss plaintiff has suffered, the Court will presume that plaintiff has suffered an economic loss at this stage of the proceedings.[3] As discussed *supra*, common law claims for defective products seeking economic loss damages are not abrogated by the OPLA. *Simpson*, 2020 WL 5629092 at *7; *Dates*, 2020 WL 3265537 at *3; *Johnson v. Wal-Mart Stores East, Inc.*, 2018 WL 1083269, *4 (N.D. Ohio 2018) ("Although R.C. § 2307.71(A)(13) abrogates common law product liability claims, there is an exception: consumers not in privity with the manufacturer seeking economic damages suffered due to damages to the product in question may bring common law claims."); *Hoffer v. Cooper Wiring Devices, Inc.*, 2007 WL 1725317 *2 (N.D.Ohio 2007) ("[T]o the extent Plaintiff seeks damages for economic loss, his claims do not fall under the purview of the OPLA.")

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[3] Indeed, economic loss only encompasses "direct, incidental, or consequential pecuniary loss, including, but not limited to, damage to the product in question, and nonphysical damage to property other than that product." O.R.C. §2307.71(A)(2). This provision specifically excludes physical injury and serious emotional distress as an economic loss. O.R.C. §2307.71(A)(2); (7). Therefore, the Court cautions plaintiff that her allegations that the product caused her bodily harm and emotional distress are preempted by the OPLA, as are any claims for the types of damages listed under §2307.71(A)(7).

However, the larger issue is whether or not plaintiff can simultaneously pursue this claim with her OPLA claims. Courts within this circuit are divided as to whether or not a plaintiff can bring both a common-law negligence claim seeking only economic loss damages and OPLA claims within the same suit. *See Huffman*, 961 F.Supp.2d at 882 (N.D. Ohio 2013) (finding a plaintiff is "allowed to bring both common-law and OPLA claims" within the same suit); *Great Northern Ins. Co. v. BMW of N. Am. LLC*, 84 F. Supp. 3d 630, 649 (S.D. Ohio 2015) ("[T]his Court holds that Plaintiffs are permitted to argue in the alternative, and bring their OPLA claims for compensatory damages, and their common implied warranty claim for purely economic damages, under the same set of facts."); *Dates*, 2020 WL 3265537, *2 (finding "there is no good argument" as to why these claims cannot be brought simultaneously); *Federated Rural Electric Management Corp. v. Electro Switch Corporation*, 2020 WL 3255144, *3 (S.D. Ohio 2020). *Cf. Meta v. Target Corp.*, 74 F. Supp.3d 858, 864 (N.D. Ohio 2015) (finding a plaintiff "may not carve out a common law product liability claim for economic loss only where . . . the facts underpinning his common law claims constitute the same conduct [giving rise to his OPLA claim]"); *Mitchell v. Proctor & Gamble*, 2010 WL 728222, *2 (S.D. Ohio 2010) (holding that plaintiff could not bring a common law negligence claim for economic damages where the conduct that forms the basis of the negligence claim is the same conduct giving rise to the OPLA claim).

Courts finding that these claims may be brought simultaneously have noted that the recovery of economic losses in an OPLA claim is contingent on the recovery of compensatory damages. *Huffman*, 961 F.Supp.2d at 881-882; *Dates*, 2020 WL 3265537 at *2. *See also* O.R.C. § 2307.79. These courts have reasoned that prohibiting a plaintiff from bringing both claims

would "require plaintiffs to chose between a relatively certain recovery of economic loss damages and the possible recovery of compensatory damages plus economic loss damages." *Huffman*, 961 F.Supp.2d at 881-882. *See also Dates*, 2020 WL 3265537 at *2 ("This backstop is necessary because a receipt of compensatory damages is a prerequisite for receiving economic loss damages on the OPLA claim.") These courts have also observed that a plaintiff has the procedural right to assert alternative theories under the Federal Rules of Civil Procedure. *Huffman*, 961 F.Supp.2d at 881; *Great Northern Ins. Co.*, 84 F. Supp. 3d at 649. *See also* FRCP 8(d)(2) ("A party may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones.")

Courts opposed to allowing both claims to proceed have characterized a plaintiff's attempt to do so as "dressing up" an OPLA claim as a negligence claim. *Mitchell*, 2010 WL 728222 at *4. These courts have reasoned that a plaintiff should not be able to bring a common law negligence claim for economic damages where the "actionable conduct that forms the basis of the negligence claim-negligent research, manufacturing, testing, marketing, and failure to warn-is the same conduct that the OPLA defines as giving rise to a products liability claim." *Mitchell*, 2010 WL 728222 at *4. *See also Meta*, 74 F.Supp.3d at 864 ("Mr. Meta may not carve out a common law product liability claim for economic loss only where . . . the facts underpinning his common law claims constitute the same conduct that gives rise to the product liability claim.")(internal quotations omitted) This rationale is partly based on the fact that the OPLA expressly allows for plaintiffs to recover economic losses in a product liability action and, therefore, they are not without recourse when seeking economic damages. *Meta*, F.Supp.3d at

863-864.[4]

Upon review, the Court finds that the rationale of allowing these claims to be pursued simultaneously is more persuasive. Plaintiff should be able to bring both OPLA claims for compensatory damages and a common law negligence claim for purely economic loss.

Accordingly, plaintiff's common law negligence claim may proceed, but only to the extent that plaintiff seeks economic loss damages. The Court DENIES defendants' Motion to Dismiss as to Count One.

II. Defective Design (Count Two)

Count Two is a claim for strict product liability for defective design under O.R.C. § 2307.75. Defendants argue that this claim should be dismissed on the basis that plaintiff has not (1) plausibly alleged that the product's risks outweigh its benefits or (2) identified a "specific safer feasible alternative design." According to plaintiff, the Complaint alleges sufficient facts to establish a defective design claim.

"Ohio law authorizes recovery for injuries incurred as a result of a defectively designed product." *Miller v. Uniroyal Technology Corp.*, 35 Fed.Appx. 216, 218-219 (6th Cir. 2002) (citing O.R.C. § 2307.75(A)). The provision pertaining to defective design claims, O.R.C. § 2307.75, provides:

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[4] Defendants also argue that because plaintiff was able to use the product for its intended purpose, i.e., the treatment of stress urinary incontinence, plaintiff should not be permitted to bring a common law claim for economic loss. Defendants draw this argument from *Meta*, which observed that when courts have allowed common law negligence claims to proceed "the plaintiff suffered an injury that consisted of not being able to use the product for its intended purpose." *Meta*, 74 F.Supp.3d at 863. However, it does not appear that plaintiff was able to use the product for its intended purpose, given that she had it surgically removed.

> a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section.

O.R.C. § 2307.75(A). A multi-factor balancing test to be used when assessing foreseeable risks and benefits is set forth in O.R.C. § 2307.75(B) and (C). Courts within this Circuit have additionally required that a complaint "contain factual allegations as to which portions of the product failed." *Grubbs v. Smith & Nephew, Inc.*, 2020 WL 5305542, *5 (S.D. Ohio 2020). *See also Grange Mutual Casualty Co. v. Optimus Enterprises, Inc.*, 2016 WL 3078956, *3 (N.D. Ohio 2016); *Oblak v. Integra Lifesciences Corp.*, 2017 WL 1831098, *2 (N.D. Ohio 2017); *Johnson v. Wal-Mart Stores East, Inc.*, 2018 WL 1083269, *4 (N.D. Ohio 2018).

Upon review, the Court concludes that plaintiff's allegations, if accepted as true, sufficiently allege a claim for defective design under O.R.C. § 2307.75. The Complaint identifies the part of the product that failed: the polyproplylene mesh, which when used for pelvic floor repair, promotes "severe foreign body reaction[s] and chronic inflammatory response in a large subset of the population." This mesh is known to cause complications, such as degradation, fragmentation, shrinkage, and a high rate of failure in patients. The FDA has issued warnings regarding the complications and risks associated with pelvic mesh products, including the product. These allegations are enough to create a plausible inference that the foreseeable risks associated with the product's design outweighed its benefits.

The Complaint admittedly does not balance all of the risk/benefit factors contained in O.R.C. § 2307.75(B) and (C), including the existence of an alternative design. However, this is not necessary at this stage in the proceedings. *See Thompson v. DePuy Orthopaedics, Inc.*, 2014

WL 2874268, *5 (S.D. Ohio 2014) ("[A] plaintiff is not required to set forth specific facts addressing the multi-factor balancing test set forth in Ohio Rev. Code § 2307.75 to survive a motion to dismiss."); *Boroff v. Alza Corp*., 685 F.Supp.2d 704, 709 (N.D. Ohio 2010) ("But there would appear to be little benefit to forcing a plaintiff, as a matter of pleading, to assert legal conclusions corresponding to the elements of the complicated multi-factor balancing test set forth in R.C. § 2307.75.")

Defendants argue that this claim requires dismissal because the Complaint does not identify a specific alternative design. As noted above, the availability of an alternative design is one of the factors listed under O.R.C. § 2307.75(C). In addition, the OPLA provides that a product cannot be considered defective if "at the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available." O.R.C. § 2307.75(F). However, plaintiff is not required to identify the exact alternative design available at this point.[5] Regardless, construing the allegations in a light most favorable to plaintiff, the Complaint raises a plausible inference that a practical and feasible alternative design does exist: a pelvic mesh product not containing polypropylene mesh. Indeed, the Complaint alleges that scientific evidence has shown that this material is "biologically incompatible with human tissue" and when used for pelvic floor repair, results in significant

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[5] Defendants rely on *McGrath v. Gen. Motors Corp*., 26 Fed.Appx 506 (6th Cir. 2002) in support of their argument that plaintiff is required to identify a specific alternative design at the pleadings stage. In *McGrath*, the Sixth Circuit held that in a defective design claim brought under the OPLA, a plaintiff must present proof of an alternative feasible design. *McGrath*, 26 Fed.Appx at 510. However, *McGrath* was decided on summary judgment, not on a motion to dismiss. The Sixth Circuit did not hold, as defendants suggest, that a plaintiff is required to identify a specific feasible alternative design or engage the multi-factor risk/benefit balancing test within the complaint. *See Johnson*, 2018 WL 1083269 at *4 ("*McGrath* does not address pleading requirements.")

complications. The Complaint asserts that there are "available feasible alternatives that do not involve the same risks."

Accordingly, plaintiff has sufficiently alleged a claim for defective design under O.R.C. § 2307.75. The Court DENIES defendants' Motion to Dismiss as to Count Two.

III. Manufacturing Defect (Count Three)

Count Three is a claim for strict product liability for a manufacturing defect under O.R.C. § 2307.74. Defendants argue that this claim should be dismissed on the basis that plaintiff has not plausibly alleged how the product implanted in her deviated from its design specifications. According to plaintiff, she has alleged sufficient facts to establish a manufacturing defect claim.

Under the OPLA,

> A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

O.R.C. § 2307.74.

Upon review, the Court concludes that plaintiff's allegations do not sufficiently allege a manufacturing defect claim under O.R.C. § 2307.74. Beyond citing to O.R.C. § 2307.74, the Complaint does not contain any allegations to support this claim. Indeed, the Complaint contains no allegations that the plaintiff's implant was different from any other Gynecare TVT Abbrevo Mesh implants, or that her implant deviated in any way from defendants' specifications or standards. The Complaint does not reference any manufacturing practices or quality control methods that defendants failed to maintain in the manufacture of her particular implant. *See*

Boroff v. Alza Corp., 685 F.Supp.2d 704, 708 (N.D. Ohio 2010) (dismissing manufacturing defect claim where the complaint was "bereft of any allegation that [the product used by plaintiff] deviated from any design specifications, formula, or performance standards").

Plaintiff argues that the Complaint alleges "sufficient facts to show that a plausible inference exists between a defect in the manufacture of the product and the injuries she sustained." However, it is clear from a review of the Complaint that plaintiff takes issue with the design of the product in general, rather than a manufacturing defect contained within her specific implant. Indeed, the Complaint alleges that the specific nature of the defect includes (1) the use of polypropylene; (2) the design of the product to be inserted in an "area of the body that is blood vessel rich, nerve dense, and bacteria laden;" (3) biomechanical issues with the design; (4) the propensity of the mesh design for "plastic deformation when subjected to tension both during implantation and once implanted inside the body;" (5) the propensity of the product to become rigid and inflexible; (6) the propensity of the product for degradation or fragmentation over time; and (7) the inability of surgeons to "effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue." Each of these alleged defects relate to defendants' design of the product, rather than a deviation from design specifications or performance standards that occurred during manufacturing.

Accordingly, plaintiff has not sufficiently alleged a claim for a manufacturing defect under O.R.C. § 2307.74.[6] The Court GRANTS defendants' Motion to Dismiss as to Count

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[6] Plaintiff, without argument or support, also asks for an opportunity to amend the Complaint. Such a request is not properly made in a response to a motion to dismiss. Accordingly, this request is denied. *See Kuyat v. BioMetric Theraputics, Inc.*, 747 F.3d 435, 444 (6th Cir. 2014) ("Both because the plaintiffs did not present an adequate motion and because they did not attach a copy of their amended complaint, the district court did not abuse its discretion in refusing to

Three.

IV. Failure to Warn (Count Four)

Count Four is a claim for strict product liability for failure to warn under O.R.C. § 2307.76. Defendants argue that this claim should be dismissed on the basis that plaintiff has not sufficiently alleged why the warnings provided to her physician were inadequate. According to plaintiff, she is not required to overcome the learned intermediary defense in the Complaint.

The OPLA provides that a product is defective due to inadequate warning or instruction if the manufacturer (1) knew or should have known about a risk that is associated with the product and that allegedly caused harm for which the plaintiff seeks to recover compensatory damages and (2) failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk. O.R.C. § 2307.76(A). This section further provides:

> An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

O.R.C. § 2307.76(C). This last provision is referred to as the "learned intermediary doctrine." *Wimbush v. Wyeth*, 619 F.3d 632, 637 (6th Cir. 2010). Under this doctrine, a manufacturer's duty to warn can be discharged by providing a learned intermediary, such as a physician, with an adequate warning for the product. *Howland v. Purdue Pharma, L.P.*, 104 Ohio St.3d584, ¶24 (Ohio 2004).

> allow the plaintiffs to amend their complaint based on the final sentence of the plaintiffs' memorandum in opposition.")

Upon review, the Court finds that the Complaint's allegations, if accepted as true, sufficiently allege a claim for failure to warn under O.R.C. § 2307.76. The Complaint alleges that while "some of the problems associated with the [product were] made known to physicians, the magnitude and frequency of those problems were not disclosed and were hidden from physicians." The Complaint further alleges that defendants failed to adequately warn both plaintiff and her health care providers of twenty different "subjects" associated with the product. Included within these twenty "subjects" was the risk of corrective or revision surgery to adjust or remove the product. The Complaint then ties this risk to the injury suffered by plaintiff: surgical removal of the product. These allegations support a plausible inference that defendants failed to adequately warn a learned intermediary of the risk for which plaintiff seeks compensatory damages.

Defendants maintain that this claim is subject to dismissal because the Complaint fails to specify what written materials accompanied the product, how the warnings given to her physician were inadequate, and what her physician would have done differently if warned of the alleged risks. However, plaintiff is not required to be that precise at this juncture. *See Williams v. Boston Scientific Corp.*, 2013 WL 1284185, *5 (N.D. Ohio 2013); *Thompson*, 2014 WL 2874268 at *7 ("Whether the physician would have changed his prescribing conduct goes to the issue of proximate cause, which is not properly decided on a motion to dismiss where, as here, the allegations give rise to at least a plausible inference that the physician may have changed course upon receiving the requisite warning.") Construing the allegations in a light most favorable to plaintiff, the Complaint raises the plausible inference that had the plaintiff's health care providers been aware of the twenty different risks this product posed, they may have chosen

a different treatment course for plaintiff.[7]

Accordingly, plaintiff has sufficiently alleged a claim for failure to warn under O.R.C. § 2307.76. The Court DENIES defendants' Motion to Dismiss as to Count Four.

V. Nonconformance with Representation (Count Five)

Count Five is a claim for strict product liability for nonconformance with a representation under O.R.C. § 2307.77. Defendants argue that this claim should be dismissed on the basis that plaintiff has not identified any specific representation made to her regarding the product. According to plaintiff, the allegations that her doctor relied on defendants' representation that the product safely treated stress urinary incontinence are sufficient.

Under the OPLA, "[a] product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation." O.R.C. § 2307.77. "'Representation' means an express representation of a material fact concerning the character, quality, or safety of a product." O.R.C. § 2307.71(A)(14).

A plaintiff seeking to recover under O.R.C. § 2307.77 must show that (1) the manufacturer made a representation as to a material fact concerning the character or quality of

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[7] The Court also notes that both Ohio and federal courts have characterized the learned intermediary doctrine as a defense to a failure to warn claim. *Boyd v. Lincoln Elec. Co.*, 179 Ohio App.3d 559, ¶53-54 (Ohio App. 8th Dist 2008). *See also Howland*, 104 Ohio St.3d 584 at ¶32 (Moyer, C.J., dissenting) ("The appellant drug manufacturer may assert this doctrine as a defense to failure-to-warn claims."); *Mathews v. Novartis Pharmaceuticals Corp*., 2013 WL 5780415, n 4 (S.D. Ohio 2013) "A complaint need not anticipate every defense and accordingly need not plead every response to a potential defense." *Memphis, Tenn. Area Local, American Postal Workers Union, AFL-CIO v. City of Memphis*, 361 F.3d 898, 904 (6th Cir. 2004)

the product; (2) the product did not conform to that representation; (3) the plaintiff justifiably relied on that representation; and (4) the plaintiff's reliance on the representation was the direct and proximate cause of the injury *Hutchens v. Abbott Laboratories, Inc*., 2016 WL 5661582, *9 (N.D. Ohio 2016).

Upon review, the Court finds that the Complaint's allegations, if accepted as true, sufficiently allege a claim for failure to conform with representation under O.R.C. § 2307.77. The Complaint alleges that the product posed many risks, including a high rate of failure and the need for patients to undergo "re-operations." These specific risks ran "contrary to the representations and marketing the defendants presented to the medical community and patients." Defendants "omitted and downplayed the risks" posed by the product and "advertised, promoted, marketed, sold, and distributed" the product as a safe medical device, despite the fact that it was "not safe for its intended purposes." The product was marketed through "television, print, and internet advertising," as well as promotion through sales representatives.

The Complaint further alleges that plaintiff's physician "reasonably and justifiably relied" on the representation that the product was safe for the repair of stress urinary incontinence. However, plaintiff eventually required a revision surgery, one of the risks her physician allegedly was not adequately warned about by defendants. These allegations allow the Court to reasonably infer that the product did not conform to the representations made by defendants.

The Complaint does not provide the exact representations defendants provided to plaintiff or her physician, "but it does set forth facts from which the Court may plausibly infer that a representation was made and that the [product] did not conform to that representation, which is all that is required by Ohio Rev.Code § 2307.77 at the pleading stage." *Troyer v. I-Flow*

Corp., 2011 WL 2517031, *4 (S.D. Ohio 2011).

Accordingly, plaintiff has sufficiently alleged a claim for nonconformance with representation under O.R.C. § 2307.77. The Court DENIES defendants' Motion to Dismiss as to Count Five.

VI. Argument Applicable to All Claims – Shotgun Pleading

Finally, defendants argue that the entire Complaint should be dismissed because it is pled in an impermissible "shotgun" fashion. Defendants maintain that because the Complaint "incorporates by reference" the facts of the preceding paragraphs in each count, they are "left to parse the allegations of the entire Complaint to locate the operative facts that may relate to" each claim.

The Court disagrees. A "shotgun pleading occurs when it is virtually impossible for a defendant to know which allegations of fact are intended to support which claims for relief." *King v. G4S Secure Solutions (USA), Inc.*, 2019 WL 858672, *4 (N.D. Ohio 2019) (internal quotations omitted). Shotgun pleading also occurs when a complaint fails to separate each cause of action or claim for relief into separate counts. *Lee v. Ohio Education Association*, 951 F.3d 386, 392-392 (6th Cir. 2020). Here, the Complaint contains numerous, specific factual allegations and each cause of action is separated into five separate claims for relief. It is clear upon reading the Complaint which factual allegations are intended to support which claims for relief.

Accordingly, the Complaint is not subject to dismissal due to improper "shotgun pleading." The Court DENIES defendants' Motion to Dismiss as to this argument.

CONCLUSION

For the foregoing reasons, Ethicon, Inc. and Johnson & Johnson's Motion to Dismiss

(Doc. 12) is GRANTED in part and DENIED in part. Specifically, Count Three of the Complaint is dismissed and Counts One, Two, Four, and Five of the Complaint will proceed.

IT IS SO ORDERED.

/s/ Patricia A. Gaughan
PATRICIA A. GAUGHAN
United States District Judge
Chief Judge

Dated: 12/4/20